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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,618	04/11/2006	Venkata Satya Nirogi Ramakrishna	SUB 0006 US	9138

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EXAMINER	
SACKEY, EBENEZER O	
ART UNIT	PAPER NUMBER
1624	
MAIL DATE	DELIVERY MODE
04/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,618	RAMAKRISHNA ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,13,15,16,20,26 and 31* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,13,15,20,26 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-4, 6-7, 13, 15-16, 20, 26 and 31 are pending.

Note the Examiner of record has changed from Emily Berndhart to Ebenezer Sackey.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on 11/14/08 is acknowledged and has been entered into the file. A signed copy of the 1449 is attached herewith.

Response to Restriction

Applicant's election with traverse of Group I, claims 1-4, 6-7, 13, 15-16, 20, 26 and 31 in the reply filed on 05/29/09 is acknowledged. The traversal is on the ground(s) that improper standard has been applied to the restriction. This is not found persuasive because contrary to applicants assertion, the various Groups i.e., I-X define ten distinct inventions each capable of supporting its own patent as for example a reference rendering obviousd the methods of group IV would not necessarily be used to reject Group I compounds and compositions. Additionally, the sulfonyl compound of group I (formula (I) not further fused) is distinct from the intermediate compound of formulae (II) or (XI) of Groups VII and VIII. However, all of applicants request for the examination of current claims will be granted except claim 16.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-7 and 13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 and 13 provide for the use of compounds of claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 20 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the phrases “derivative”, “analog” “pro-drug” and “N-oxide” cannot be ascertained. It is not clear if a derivative of formula (I) is a *pro-drug or* another form of the compounds of formula (I).

Subscript “n" in formula (I), claim 1 has not been defined thus, rendering the claim indefinite.

In claims 1 and 20 respectively, the phrase ---may be same or different--- and the phrase ---preparing a--- have been repeated more than once. Additionally, in claim 20, the process is outside the scope of the elected invention since substituent "A" has been limited in the restriction requirement in the previous office action to only **carbon** and **not** C=O or SO_2. Additionally, the definition of "A" as ----may be carbon only---- connotes the presence of another variable in addition to carbon. Correction is required.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 20 recites the broad recitation X is halogen, and the claim also recites preferably chloro, bromo or iodo which is the narrower statement of the range/limitation.

Claim 26 recites the limitation "prodrug" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The plethora of intended uses present in the claims render the intended "amount" ambiguous since it is not conceivable that the dosage regimens for uses as varied as anxiety vs. ADHD vs. Parkinson's disease vs. psychotic depression vs. migraine headache would all be the same and there is nothing in the specification pointing to a particular regimen for the many uses recited. It is suggested that the uses be deleted since only one use in needed to support such a claim for compliance with 35 U.S.C. 112 and 101. See the last paragraph of MPEP 2164.01(c), November 2005 edition.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds on pages 45-85, do not reasonably provide enablement for solvates or prodrugs of those compounds. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims recite specific compounds of structural formula (I) and solvates and prodrugs of said compounds. However, the specification fails to teach the preparation of solvates or prodrugs. Therefore, the specification is not adequately enabled for solvates or prodrugs.

Note Vippagunta, provided with this action, who flatly states on page 18, section 3.4 the following: "Predicting the formation of solvates or hydrates of a compound…..is complex and difficult."

With respect to solvates, the examples presented all fail to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.,* 28 USPQ .2d 1190 "the specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However, …. there is no evidence that such compounds exist….. the examples of the '881' patent do not produce the postulated compounds…..there is ….no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compositions actually exist; if they did, they would have been formed. Hence, applicants must now show that solvates and prodrugs can be made, or limit the claims accordingly.

Applicants have not provided any reasonable assurance that any and all known prodrugs will have the ability to regenerate *in vivo* to the instant compounds by one or more biological processes. It is not the norm that one can predict with any accuracy a

particular prodrug form of an active compound will be more soluble, more easily handled in formulations or more bioavailable without actual testing *in vivo*. The specification provides no guidance as to what type(s) are suitable for instant compounds. Generally, prodrugs themselves are not considered to be therapeutically active but only to provide the active compound *in vivo*.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.
2) State of prior art.
3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure
4) Level of predictability in the art.
5) Amount of direction and guidance provided by the inventor.
6) Existence of working examples.
7) Breadth of claims.
8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is the preparation of compounds and compositions under the genus of structural formula (I). As stated, however, prodrugs, solvates are also intended. The nature of the prodrug is not set forth much less location of attachment.

2) State of the prior art.

The state of the prior art is that prodrugs, solvates are known in the pharmaceutical industry.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue. For example, identifying a metabolite or prodrug requires knowledge of degradation pathways of the instant compounds *in vivo* and nothing short of extensive testing (none identified) would be needed to determine if additional derivatives exist. Additionally, not all metabolites are necessarily active themselves and thus, such a scope as literally claimed herein is non-enabled.

4) Level of predictability in the art.

The art pertaining to the preparation and use of prodrugs, solvates are high as prodrugs are compound specific and not all prodrugs have the ability to regenerate *in vivo*.

5) Amount of direction and guidance provided by the inventor.

There is no guidance provided as all the examples in the specification are drawn to the preparation of compounds and not prodrugs or solvates. Additionally, the specification provides no guidance as to what type(s) prodrugs or solvates are suitable for the instant compounds.

6) Existence of working examples.

No examples of prodrugs or solvates have been provided in the specification.

7) Breadth of claims.

The breath of the recited compounds and the prodrugs or solvates renders the claims overly broad.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high due to the unpredictability in the chemical art.

Hence, the specification fails to provide sufficient support for prodrugs, solvates as claimed herein. As a result, necessitating one of ordinary skill in the art to perform an exhaustive search to determine which of the claimed prodrugs or solvates can be employed to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EBENEZER SACKEY whose telephone number is (571)272-0704. The examiner can normally be reached on 7.30-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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